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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,967	08/16/1999	KANWARPAL S. DHUGGA	5718-55	4392

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EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

14

DATE MAILED: 05/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/374,967

Applicant(s)

DHUGGA ET AL.

Examiner

Mary M. Schmidt

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 April 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,3-5,7-13,23,24,32,33 and 41-45.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1, 3-5, 7-13, 23, 24, 32, 33 and 41-45 stand rejected under 35 U.S.C. 112, first paragraph, for lack of written description and scope of enablement as set forth in the Official Action mailed 01/02/02. The claims remain broadly drawn to a nucleotide sequence encoding any maize or leguminous plant GDP-mannose pyrophosphorylase. It is noted on page 5 of Applicants' response to the outstanding lack of written description rejection that MPEP 2163.02 states that the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor has possession at that time of the later claimed subject matter." The arguments raised on page 5 were originally raised in the response made 10/09/01. Applicant has reiterated some of the Examiners' response. Applicant further writes that "It is respectfully submitted that the proper inquiry is not whether or not an artisan is likely to encounter one or more inoperative embodiments while screening for operative embodiments within the scope of the present invention. Rather, the inquiry should focus on whether one of skill in the art would, given the guidance provided by the specification, have a reasonable expectation of success in making isolated sequence commensurate with the scope of independent claims 1, 24 and 33 without having to perform more effort than is normally required in the art. the applicants point out that a variety of functional assays are described in the specification at page 17, line 28 through page 18, line 3. It is the very provision of such screening systems that enables practitioners of the biotechnological arts to select that which is desired from that which is not. The screening of a group of sequences containing from a few to many, inoperative species in order to isolate one or more operative species is a common practice in many aspects of the biotechnological arts. With the guidance provided in the specification as cited herein and in the previous response, isolation of operative embodiments from a group of candidate sequences as claimed in current independent claims 1, 24, and 33, clearly has a reasonable expectation of success by one skilled in the art and would reasonably convey that the inventor had possession of the claimed subject matter." In response, Applicant is referred to MPEP 2163 IA: "The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between the that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.... A lack of written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." In the instant case, the claims as amended read on any maize or leguminous plant GDP-mannose pyrophosphorylase. Applicants have stated that the examination should focus on whether or not an artisan is likely to encounter one or more inoperative embodiments while screening for operative embodiments within the scope of the invention. Such an analysis pertains more to a scope of enablement rejection discussed below. From the sections of the MPEP newly cited, it is more clearly stated that the claimed function of a nucleic acid sequence, ie. in the instant case the function of GDP-mannose pyrophosphorylase, does not clearly describe the sequence of the claimed nucleic acids encoding such a protein so that one skilled in the art would be able to envision Applicants' claimed invention to understand that Applicant was in possession of a representative number of species of such sequences having the claimed function. In the instant case, Applicant has disclosed two nucleic acid sequences having the claimed function. However, as argued previously, the disclosure of the sequences, coupled with the teachings of the specification and the art, do not show one skilled in the art any description of any other nucleic acid sequence which would also be considered a maize or leguminous plant GDP-mannose pyrophosphorylase. Specifically, description of key structural elements, ie. key sequence structural elements, of any such maize or leguminous plant GDP-mannose pyrophosphorylase were not provided at the time the invention was made. Applicants' references to well known assays in the art such as Northern Blots for detection of other such sequences does not define a correlation between such assays and specific sequences to search for which are indicative of any other sequence having the function of a maize or leguminous plant GDP-mannose pyrophosphorylase. Thus, one of skill in the art would not have been able to visualize a representative number of such sequences and the claims as amended continue to lack written description for the breadth of any maize or leguminous plant GDP-mannose pyrophosphorylase nucleotide sequence, expression cassettes, plant cells or plants comprising said sequences.

Applicants' response to the outstanding scope of enablement rejection states that "sequences that do not function as a plant GDP-mannose pyrophosphorylase (i.e. inoperative embodiments) are not claimed. Applicant writes that "one skilled in the art would reasonably expect that those nucleic acid molecules that have at least 90% identity to SEQ ID NO:1, and possess GDP-mannose pyrophosphorylase activity could be used in the previous claimed invention. the skilled artisan would recognize that the limitations of present Claim 1 are such that a majority of nucleic acid sequences encompassed by the claim would be expected to be functional. The functional and structural limitations of present claim 1 preclude undue experimentation." In response, claim 1 is drawn not only to sequences that are 90% homologous to SEQ ID NO:1, but also to any maize or leguminous plant GDP-mannose pyrophosphorylase. The rejection remains over any such sequence for the same reasons argued previously since it would require more than routine experimentation to discover any such sequence having the claimed functions. However, the breadth of 90% homology to the specific claimed sequences is considered enabled for the reasons stated by Applicant.

Therefore, Applicants' response has not overcome all the outstanding 35 U.S.C. 112, first paragraph, final rejections for the reasons stated above.

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